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09/471,255	12/23/1999	JOSEE HAMEL	55190-012	7195

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	17

DATE MAILED: 12/07/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/471,255	Hamel et al
Examiner	**Art Unit**
Portner	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 19, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *16-20 and 25* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-31* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4, 6-8*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claims 1-31 are pending.

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

2. The information disclosure statements filed March 21, 2000, May 2, 2000, May 26, 2000 and November 16, 2000 have been considered prior to this action.

Election/Restriction

3. Applicant's election with traverse of Group II, (claims 16-20 and 25), SEQ ID NO 2 in Paper No. 16, dated September 19, 2001 is acknowledged. The traversal is on the ground(s) that the polynucleotides of Group I encode the polypeptides of Group II and that "Applicant's invention in claim Group II (and Group I) covers only the polypeptides and polynucleotides for (1) the BVH-3 gene. Therefore, claims in the elected Group II (and Group I), drawn only to SEQ ID NOS: 2,4,6,8, 10, 14, 16, 55 to 75, 77 to 79, 81, 83 or fragments, analogs or derivatives thereof, are all derived from the same BVH-3 gene."

4. These arguments have been fully considered but are not found to be persuasive for the reasons below. Upon consideration of the disclosure in the instant Specification, the examiner

found that SEQ ID NO 4 and 6 are amino acid sequences encoded by genes that are not BVH-3, but designated BVH-11 and BVH-28, respectively. All of the SEQ ID Nos are not encoded by BVH-3 genes. The claims of Group II do not recite just species of BVH-3, but recite independent and distinct products. The separate polypeptides bear no structural or biochemical property in common and therefore each particular protein product claimed would require a separate area of search and consideration tailored to the particular product under consideration. Claims 16-20 and 25 are not generic claims.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1)independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups I-V are drawn to distinct inventions which are related as separate products capable of separate functions, wherein all of the claimed polypeptides are not encoded by the same gene, and would not encode the same or equivalent polypeptide. Restrictions between the inventions is deemed to be proper for the reason previously set forth. With respect to Applicant's

arguments with respect to rejoining Groups I and II, it is the position of the examiner that the polynucleotides of Group I and the polypeptides of Group II differ in structure, function and effect, and the polypeptides are obtainable from natural sources and need not be produced recombinantly based upon the polynucleotides of Group I.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups I-V are classified separately necessitating different searches of issued US Patents., However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example polypeptides and polynucleotides have different biological functions. Additionally, it is submitted that the inventions of Groups I-V have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made Final.

Sequence Compliance

5. The instant Application is now in sequence compliance.

Specification

6. The disclosure is objected to because of the following informalities: At page 1, line 3, the word --December-- should evidence a capital letter and a comma "," should follow immediately after the number "23". At page 2, line 16, the word -- May-- should evidence a capital letter. At page 35, line 4, the term "S.pneumoniaenucleic" is recited; this should be broken into two separate words. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 16-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, credible and substantial asserted utility or a well established utility.

The instant specification discloses SEQ ID No 2, an amino acid sequence and the polynucleotide that encodes the polypeptide, as well as suggests fragments, analogs and derivatives of SEQ ID No 2, but the claimed invention is directed to an isolated polypeptide that shares 70% sequence identity with an amino acid sequence of SEQ ID No 2 (claim 16), or only shares an epitope of SEQ ID NO 2 (claim 17), or is an analog, fragment analog or derivative of SEQ ID NO 2 (claim 18-20), and are not required to have any specific biological function, nor

are they described as having any specific, credible and substantial asserted utility or a well established utility.

None of these claimed embodiments have been characterized as having enzymatic, adhesive characteristic, toxin activity or correspondence to any other proteins which are known to be associated with similar types of bacteria. The use of any polypeptide or polypeptide fragment for a vaccine would not be predictable in the art of vaccines. Boslego shows a well characterized Mycobacterium protein which is highly immunogenic but does not induce a protective immune response. Vaccines are not predictable until the composition has been shown by substantive evidence that the polypeptide has the asserted characteristic. Therefore, an asserted utility of a vaccine would not be credible in the vaccine art, especially for a vary small portion of a polypeptide which may or may not have any immunogenic epitopes contained therein. Without specific teaching of a substantive utility the person of skill in the art would not be able to use the claimed invention for any known purpose, such as diagnostics or vaccines. The utility of the polypeptide has not been defined.

As no specific, credible and substantial utility for the recited SEQ ID NO 2 fragments, analogs, analog fragments, derivatives, polypeptides that only share an amino acid sequence with a second polypeptide sequence and polypeptides that share an epitope with SEQ ID NO 2, has been disclosed. The claimed invention of a polypeptide that only shares an amino acid sequence with a second polypeptide fragment, analog, or derivative and polypeptides that share only an epitope, have not been shown to evidence a well established utility, such as an enzyme, that is

useful in the metabolism of a reagent or in the screening of inhibitors to effect the viability of a known pathogen.

Credible utility used herein refers to the reliability of the statement based on the logic and facts that are offered by the instant specification in support for the assertion of utility. If a polypeptide is not defined by specific functional characteristics, such as where the polypeptide is located in the bacterium, specifically an intracellular protein, membrane surface protein or a secreted protein, the availability of the bacterial protein to induce an immune response in a host would be in question, could the protein be used as a diagnostic polypeptide. If no information is provided describing where or how the protein is presented or functions, the use of the protein as a specific marker for diagnostic purposes could not be carried out. As polypeptides(proteins) are known to be antigenic, the characteristic of being a diagnostic marker for a bacterial infection or disease in not readily apparent merely by a composition being a protein because all proteins are not diagnostic markers for infection and could be a protein which shares cross reactivity with other bacteria. Therefore the polypeptide would not be specific for identifying the bacteria. If the assertion of a characteristic is credible, the claimed invention would also need to evidence specific utility for claimed subject matter.

With a substantial utility, the invention is defined for a real world use. Utilities which require or constitute carrying out further research to identify or reasonably confirm a real world context of use does not define a substantial utility. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease

condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. Circular reasoning to define a utility does not define a substantive utility. For example, when a protein or antigen fragment is used to stimulate the production of antibodies so the antibodies can be used to identify the protein, the use of the protein is not specific or substantial to anything other than a protein that does not correlate with anything other than itself. A person would not readily use a polynucleotide to produce a protein that does not correlate with anything associated with a bacteria because the protein has not been shown to be specific to that bacteria, nor has the protein been shown to have any credible use that is substantially applicable for testing, discovering or associated with conditions that effect the context of its use.

Absent factual evidence, a percentage sequence similarity of less than 100 % is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement. Several publications document this unpredictability of the relationship

between sequence and function, albeit that certain specific sequences may be found to be conserved over biomolecules of related function upon a significant amount of further research. See the following publications that support this unpredictability as well as noting certain conserved sequences in limited specific cases: Gerhold et al.[BioEssays, Volume 18, Number 12, pages 973-981{1996)]; Wells et al.[Journal of Leukocyte Biology, Volume 61, Number 5, pages 545-550 (1997)]; and Russell et al.[Journal of Molecular Biology, Volume 244, pages 332-350 (1994)].

The instant specification does not disclose that the claimed polypeptides correlate or have a well established utility known in the art as being specific, substantial and credible and would be readily apparent or implied by the properties of the material, alone or taken with the knowledge of one skilled in the art.

8. Claims 16-20 and 25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, credible and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 U.S.C. § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 16-20 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the phrase "an amino acid sequence chosen from SEQ ID NO 2". As SEQ ID NO 2 is an amino acid sequence of 1039 amino acids, how many and what amino acids are chosen from SEQ ID NO 2? The amino acid sequence chosen need not be a sequence of consecutive amino acids, may be an amino acid sequence of any size (fragment), may be an analog or a derivative of SEQ ID No 2. What is the claimed isolated polypeptide that must only share sequence identity with an amino acid sequence of SEQ ID NO 2 or a SEQ ID No analog or derivative?

SEQ ID No 2 ----------

Having an amino acid sequence of SEQ ID NO 2 that is 70% identical

↕

Claimed ^^^^^^^^^^^^^^^/----^---^^/^^^^^^^

^: an amino acid that differs from that of SEQ ID NO 2.

-: an amino acid that is identical to reference sequence SEQ ID NO 2

Claim 16 is directed to any polypeptide of any size, that is not required to have any biological function. What is the biological function of the isolated polypeptide? How would one know which derivative or analog would be within the scope of the invention, if the polypeptide does not have any identifying characteristics? The meets and bounds of the claim are not clearly set forth. Clarification is requested.

Claim 17 recites the phrase "An isolated polypeptide capable of generating antibodies having binding specificity for a second polypeptide". The claimed polypeptide could be a polypetpide that has binding specificity for the second polypeptide or the antibodies could have binding specificity for the second polypeptide. Which of the two molecules recited prior to the phrase "second polypeptide" must evidence binding specificity for the second polypeptide? What is the biological function and amino acid sequence of the second polypeptide that is an analog or derivative of SEQ ID NO 2?

Claim 17 recites the phrase "capable of generating antibodies having binding specificity for a second polypeptide". While it is clear that the antibodies must bind first and second polypeptides, what is the binding specificity of the antibodies in light of the claim not specifically defining to what sequence the antibodies bind and the claims reciting analogs and derivatives of SEQ ID NO 2 which could define epitopes not present in SEQ ID NO 2 and the claimed isolated polypeptide need not generate antibodies that only specifically bind to SEQ ID NO 2 ?

Claim 18 recites the phrase "An isolated polypeptide having an amino acid sequence chosen from SEQ ID NO 2". What is the amino acid sequence that the isolated polypeptide has in common with SEQ ID No 2, a SEQ ID No 2 analog or a SEQ ID NO 2 derivative?

Claim 19 depends from claim 18 and recites the phrase "wherein the N-terminal Met residue is deleted". Do all fragments, analogs and derivatives of claim 18 have N-terminal Met, which then have the N-terminal Met residue deleted in claim 19? How is claim 19 further limiting of fragments, analogs and derivatives of SEQ ID NO 2 that do not have an N-terminal Met residue?

Claim 19 recites the abbreviation "Met". The utilization of abbreviations in the claims is permitted upon their definition at their first appearance. Clarification is requested.

Claim 20 depends from claim 18 and recites the phrase "wherein the secretory amino acid sequence is deleted". Do all fragments, analogs and derivatives of claim 18 have secretory amino acid sequences, which are deleted in claim 20 ? How is claim 20 further limiting of fragments, analogs and derivatives of SEQ ID NO 2 that do not have a secretory amino acid sequence? What is the secretory amino acid sequence of SEQ ID NO 2, SEQ ID No 2 analogs, SEQ ID NO 2 derivatives and SEQ ID NO 2 fragments?

Claim 25 depends from any one of claims 16-20 and is vague and indefinite for the reasons set forth above as applied to these claims, as claim 25 depends from each of these claims.

Claim 25 recites the phrase "a polypeptide" wherein "a" is an indefinate article. The claim could be made definate and the rejection could be obviated by amending the claim to recite --the-- "polypeptide".

Claim 16-20 and 25 all recite non-elected inventions. Amendment of the claims to recite only the elected invention would distinctly claim Applicant's elected invention.

12. Claims 16-20 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

The specification discloses SEQ ID NO: 2 which corresponds to a species of polypeptide obtained from S.pneumonia. SEQ ID NO: 2 meets the written description and enablement provisions of 35 U.S.C. 112, first paragraph. However, claims 16-20 and 25 are directed to encompass amino acid sequences that encode polypeptides that correspond to sequences from other sources, mutated sequences, sequences that have a recited degree of identity (similarity, homology), analogs and derivatives of SEQ ID No 2. None of these sequences meet the written description provision of 35 U.S.C. 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 2 and other specific sequences provided for BVH-3 polypeptide, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* ,

107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing

a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 2 but not the full breadth of the claim meets the written description provision of 35 U.S.C. 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. (See page 1115.)

13. Claims 16-20 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of a polypeptide consisting of SEQ ID No 2 and use of the polypeptide for the induction of a protective immune response when combined with QuilA, and immunogenic fragments for the induction of antibodies to detect SEQ ID NO 2, does not reasonably provide enablement for the use of any polypeptide that only shares an amino acid sequence of SEQ ID NO 2, is an analog of SEQ ID No 2, is a polypeptide that only shares an epitope with SEQ ID NO 2 for the induction of a protective immune response and the use of any fragment as a vaccine. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to use the invention commensurate in **scope** with these claims.

The specification does not provide substantive evidence that the claimed fragment, analog, derivative polypeptides of SEQ ID No 2 or polypeptides that only share an epitope of SEQ ID NO 2 are capable of inducing protective immunity. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing infections. Without this demonstration, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced.

The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies is problematic. Ellis exemplifies this problem in the recitation that "the key to the problem (of vaccine development) is the identification of the at protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies"(page 572, second full paragraph). Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity. See Boslego et al. wherein a single gonococcal pillin protein fails to elicit protective immunity even though a high level of serum antibody response is induced (page 212, bottom of column 2). Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

The specification does not show an protective fragments, analogs, derivatives, homologs or polypeptides that share a single epitope to induce the type of immune response that would function to protect an immunocompetent host against infection and disease. The specification fails to teach essential component, epitope that is need for the induction of a protective immune response. Further, the specification fails to provide an adequate written description of what homologs, analogs, derivatives or fragment polypeptides would be protective against Streptococcus infection. The skilled artisan would be required to de novo locate, identify and characterize the claimed other polypeptides. This would require undue experimentation given the fact that the specification is completely lacking in teachings as to other polypeptides with the claimed characteristic of a vaccine.

Claim Rejections - 35 U.S.C. § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. Claims 16-20 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by WO98/18930,(Human Genome Sciences, May 7, 1998, SEQ ID NO 182, 56 and 66).

The claimed invention is directed to an isolated polypeptide fragment of SEQ ID NO 2, which does not have the N-terminal Met or the leader sequence.

WO98/18930 discloses an amino acid sequence that shares 100% sequence identity with SEQ ID No 2 over 447 amino acids, does not have the does not have the N-terminal Met or the leader sequence (see sequence alignment provided for SEQ ID NO 182).

The reference also discloses two additional amino acid sequences that share an amino acid sequence of greater than 70% identity, wherein the disclosed amino acid sequence shares 78.6 % sequence identity with SEQ ID No 2 over 103 amino acids.

The disclosed polypeptide is a derivative of SEQ ID NO 2 as it is smaller than SEQ ID NO 2 and the amino acid sequence is derived from SEQ ID No 2.

The disclosed polypeptide is also an analog and fragment of SEQ ID NO 2, wherein an analog would evidence deletions in the claimed SEQ ID NO 2 amino acid sequence and the disclosed amino acid sequence of WO98/18930 is a fragment of SEQ ID NO 2.

Inherently the disclosed polypeptides anticipate the now claimed invention.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

December 6, 2001

LYNETTE R. F. SMITH
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